Perinatal Care at the Limits of Viability

Michelle Y. Owens, MD
Pelham Staples Symposium
Arlington, TX
Oct. 17, 2014
I have no financial disclosures.
Periviability: Case 1

✓ 15 yo G1P0 @ 23 0/7 wks gestation presents complaining of abdominal pain and pelvic pressure.

✓ SSE reveals membranes visible at the cervical os. Sonogram reveals a male fetus in breech position. Estimated fetal weight is 525g.

✓ The patient is afebrile and not tachycardic. Physical examination is otherwise unremarkable. The cervix is 2 cm dilated.

✓ Labs reveal a normal white count, and amniocentesis reveals no evidence of chorioamnionitis.
What would you do?????

✔ Fetal monitoring?
✔ Tocolysis? Cerclage?
✔ Antenatal steroids?
✔ Would your plan/counseling change if the patient was 24 weeks?
✔ 26 weeks?
✔ 22 weeks?

WHY???
Periviability: Case 2

- 42 yo P0020 @ 22 5/7 weeks with IVF twins presents in preterm labor.
- She states that she wants “everything possible done” for her babies.
- Ultrasound reveals no evidence of fetal malformations. EFWs are 450g/480g. V/V presentation.
- There is no clinical evidence of chorioamnionitis.
What would you do?????

✓ Fetal monitoring?
✓ Tocolysis?
✓ Antenatal steroids?
✓ Would your plan/counseling change if the patient was 23 weeks?
✓ 24 weeks?
✓ 26 weeks?

WHY???
“Perplexity: Inability to determine what to think or how to act, owing to the involved, intricate, or complicated condition of circumstances, or of the matters to be dealt with, generally also involving mental perturbation and anxiety.”
The limits of viability… a historical perspective:
The limit of viability....

- 11.4% PT birth rate
- Extremely LBW 1.4%
- 65,000 annually
- HP 2010 < 0.9%
- HP 2020 < 1.4%
The limit of viability.....

- Extremely preterm birth (EPT; <26 weeks) 0.4% of all births in the US
- 50% of perinatal mortality
Morbidity and mortality remains highest for the smallest and the youngest.

Those with co-morbidities are at even greater risk.

Of EPT non-survivors, ~50% die within the first 72 hours, with 75% dead by DOL 28.
Limit of viability....

✓ $26.2 BILLION (2005)
  - 16.9 billion (65%) – medical care
  - 1.9 billion (7%) – maternal delivery
  - 0.61 billion (2%) – early intervention services
  - 1.1 billion (4%) – special education services
  - 5.7 billion (22%) – lost household labor and market productivity

Caughey et al. AJOG 2014
Evidence-based practice: The challenges

- Definition of viability
- Timelines
- Variation of data reporting; “who and how”
- Effect of fetal gender, race, and other issues
- “Intangibles” difficult to quantify; “lack of objectivity”
- Which is better… gestational age or fetal weight?
- Gestational age determination
- Numbers, study design
- Variation of care available, inherent bias
- Paucity of long-term outcome data reflective of current practices.
The limit of viability...has it been reached?

<table>
<thead>
<tr>
<th>Region</th>
<th>#LVBN</th>
<th>23 weeks</th>
<th>24 weeks</th>
<th>25 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Zealand</td>
<td>167</td>
<td>9</td>
<td>72*</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>(20-26)</td>
<td></td>
<td>(24-25wks)</td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td>949</td>
<td>17</td>
<td>44</td>
<td>68</td>
</tr>
<tr>
<td>France</td>
<td>207</td>
<td>0</td>
<td>31</td>
<td>50</td>
</tr>
<tr>
<td>UK-Ireland</td>
<td>1289</td>
<td>10</td>
<td>33</td>
<td>58</td>
</tr>
<tr>
<td></td>
<td>(21-25)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Belgium</td>
<td>322</td>
<td>5</td>
<td>29</td>
<td>55</td>
</tr>
<tr>
<td></td>
<td>(22-26)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>World Review</td>
<td></td>
<td>2-35%</td>
<td>17-58%</td>
<td>35-55%</td>
</tr>
</tbody>
</table>
The limit of viability... has it been reached?

✅ EPIBel study - Pediatrics 9/2004

✅ 525 infants; 322 EPT live births (≤26 weeks)

✅ 54% overall survival

✅ <15% survival free of serious neonatal morbidity at hospital discharge (63%*)

✅ 8% BW <500g, with 36% surviving to hospital discharge
The limit of viability...has it been reached?

NICHD Neonatal Research Network – Pediatrics 107;2001

Morbidity and mortality for VLBW infants born from 1995-1996

4438 live births, 84% survived to discharge

Mortality highest for lowest BW/GA: 89% (401-500g), 71% (501-600g)
Outcome data: The EPICure Study (Pediatrics, 2000)

- Evaluate outcomes for infants born at the threshold of viability (20-26 weeks)
- 811 infants, 9 months
- 47% survival to 28 days
- 39% Survival to discharge
- 21 wks – 0%
- 22 wks - 14% ; 9%
- 23 wks – 30% ; 20%
- 24 wks – 43% ; 34%
- 25 wks – 59% ; 52%
- Failure to administer antenatal steroids was predictive of a major scan abnormality.
Outcome data:
The EPICure Study *(NEJM 2000)*

✔ Progressive decline in proportion of children with “severe” disability with increasing gestational age.
NICHD Neonatal Research Network (2010):
Perinatal care at the limits of viability...

- Obstetricians and pediatricians underestimate EPT mortality and outcome (freedom from handicap).

- Attitudes toward those at the cusp of viability has been shown to affect mortality and outcomes.
“.. For the eye sees not itself but by reflection..”
Limits of Viability: Attitudes influence Outcomes

✓ Bottoms, et al - MFM network, AJOG 1997

✓ 713 infants, >21 weeks gestation, ≤1000g

✓ Willingness to intervene results in a greater likelihood of both intact survival and survival with serious morbidity.
Limits of Viability: Attitudes influence Outcomes


- Near universal initiation of intensive care compared with selective initiation was associated with 24.1 additional survivors per 100 live births, 7.2 cases of disabling cerebral palsy per 100 live births, and a cost of 1372 additional ventilator days per 100 live births.
Limits of Viability: Attitudes influence Outcomes


- 3602 infants, 22-27 6/7 wks gestation

- 22-25 wks, proactive perinatal strategy increases the number of live births and improves the infant’s postnatal condition & survival w/o increasing morbidity (survivors up to 1 yr).
“Miracle Babies”
Beyond survival: Long term outcome.....
Miracle Babies
“Miracle Babies”
Dystonia, including Cerebral Palsy

Chronic lung disease

Behavioral problems

Growth abnormalities

Educational problems

Mental retardation

Hearing loss

Visual deficits (including blindness)

Speech delay

Cognitive deficits
Poor Outcome Predictors:

- Grade 3 or 4 IVH
- Periventricular Leukomalacia
- Posthemorrhagic hydrocephalus
- Necrotizing Enterocolitis
- Sepsis
- Chronic Lung Disease
- Retinopathy of Prematurity
Long term outcome data (US/NICHD):

- Assessed neurodevelopmental, neurosensory, and functional assessment at 18 to 22 months' corrected age.

- Neurologic, developmental, neurosensory, and functional morbidities increased with decreasing birth weight.
Long term outcome data: The EPICure Study (NEJM 2005)

- Of those with disability at 30 months of age, 86% still had moderate to severe disability at 6 years of age.

- 22% severe disability, 24% moderate disability, 34% mild disability

- Rates of survival with no disability at 6 years: 0 at 22 wks, 1% at 23 wks, 3% at 24 wks, and 8% at 25 wks.

- 12% disabling cerebral palsy (20% CP)

- 46% free of disability
EPT survivors remain at high risk for learning impairments and poor academic attainment in school.

Cognitive ability, reading, language difficulties (phonetics and speech), and mathematics
57% have special education needs, and 50% (vs. 5%) were rated as having below average attainment.

2/3 of EPT children require additional support in school.

Growth delays were noted up to age 11.*
OBSTETRIC INTERVENTIONS:
WHAT ARE WE TO DO???
(RAJU, AJOG MAY 2014)
Obstetric Interventions:

- Antenatal steroids
- Tocolytic therapy
- Magnesium Sulfate
- Latency antibiotics
- Continuous EFM
- Cesarean delivery
- Resuscitation measures (neonate)
Antenatal Steroids

✓ < 22 0/7 weeks of gestation - Not recommended

✓ (22 0/7 - 22 6/7) - Consider if delivery at ≥ 23 0/7 is anticipated

✓ Recommended ≥ 23 0/7 weeks of gestation
Tocolytics (Steroid Latency)

✔️ < 22 0/7 weeks of gestation - Not recommended

✔️ (22 0/7 - 22 6/7) - Not recommended unless concurrent with antenatal steroids

✔️ ≥ 23 0/7 weeks of gestation - Consider
Magnesium Sulfate for NP

✓ < 22 0/7 weeks of gestation - Not recommended

✓ (22 0/7- 22 6/7) - Not recommended

✓ ≥23 0/7 weeks of gestation - Recommended
Antibiotics for PPROM

- < 22 0/7 weeks of gestation – Consider if delivery not imminent.

- (22 0/7 - 22 6/7) – Consider if delivery not imminent.

- ≥23 0/7 weeks of gestation - Recommended if delivery not imminent.
GBS prophylaxis

✓ < 22 0/7 weeks of gestation - Not recommended

✓ (22 0/7 - 22 6/7) – Not recommended

✓ ≥23 0/7 weeks of gestation - Recommended
Continuous Intrapartum EFM

✓ < 22 0/7 weeks of gestation - Not recommended

✓ (22 0/7- 22 6/7) – Not recommended

✓ ≥23 0/7 weeks of gestation - Recommended
Cesarean delivery for fetal indication

✓ < 22 0/7 weeks of gestation - Not recommended

✓ (22 0/7 - 22 6/7) – Not recommended

✓ ≥ 23 0/7 weeks of gestation - Recommended
Aggressive newborn infant resuscitation

- < 22 0/7 weeks of gestation - Not recommended – comfort care only

- (22 0/7 - 22 6/7) – Not recommended unless considered potentially viable based on individual circumstances

- ≥23 0/7 weeks of gestation – Recommended unless considered nonviable (individualize).
The limit of viability: Mode of delivery……. (With apologies to W.S.)

“To “C[esarean]” or not to “C.”… that is the question. Whether ‘tis nobler in the mind to suffer
The slings and arrows of outrageous labor,
Or to take scalpel to the uterus,
And by delivering end it?
To die, to sleep; no more.”
The limit of viability: Mode of delivery......

- The data are conflicting.

- All 6 controlled trials of elective cesarean delivery terminated, 5 because of difficulty with recruitment.

- Balance benefits with risks.
Ethical dilemmas at the limits of viability….

“A time may come when a woman who miscarries at six weeks will see the fetus resuscitated against her wishes.”

-Dr. Robert Boyle
Limits of Viability: Ethical decision-making

✓ Ethical evidence in this arena is sparse.
Decisions regarding all aspects of management of the birth and subsequent care of the infant be made jointly by the parents and the physicians.

Parents receive appropriate information about maternal risks associated with delivery options, potential for infant survival, and risks of adverse long-term outcomes.

Parental choice regarding the management of the delivery and subsequent care of the infant be respected within the limits of medical feasibility and appropriateness.
Periviable births represent a small portion of all births, but are large contributors to perinatal morbidity and mortality.

Infants born at 20-21 weeks of gestation do not survive, and survival does not exceed 50% until 24 weeks of gestation.
Care in the periviable period

✓ Long term outcome data are complex, but support that risk remains highest for those born at the lowest gestational ages and weights.

✓ What we can do (the evidence):
  – Steroids
  – Antibiotics
  – Delivery in appropriate setting
Care in the periviable period

✔ The team counseling process is key (and dynamic)!

✔ Comfort care IS care.
“The care of the tiny preterm infant is a large and expensive uncontrolled experiment.”

- Silverman
The End